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DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(781)279-1675 FAX: (781)279-1742

WARNING LETTER

NWE-21-99W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

April 22, 1999

Robert Axler
President
Springfield Smoked Fish Co., Inc.
150 Switzer Street
Springfield, MA 01109

Dear Mr. Axler:

On December 9 through 18, 1998, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 150 Switzer Street, Springfield, MA 01109. The investigators documented violations of Section 402 (a)(4) of the Federal Food Drug and Cosmetic Act and Title 21, Code of Federal Regulations (21 CFR) Parts 110 "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food" (GMPs) and 123 "Safe and Sanitary Processing and Importing of Fish and Fishery Products" (Seafood HACCP Regulation), as follows:

- Corrective action taken is not appropriate, 21 CFR 123.7(c). For example, during a review of your records for hot smoked salmon on 10/19/98, the highest temperature recorded for the cold probe was [redacted]. The critical limit for this process is [redacted] for [redacted] minutes. There were also similar observations in which product was under processed and no corrective action was taken.

- Monitoring procedures are inadequate, 21 CFR 123.6(c)(4). For example, for vacuum-packaged hot and cold salmon, your firm does not identify the placement of temperature probes for full and partial loads. The placement of probes during processing is not based on any logical rationale to assure that the load is adequately processed.

- A Hazard is not listed in the HACCP plan, 21 CFR 123.6(c)(1). For example, for the hot smoking processes, histamine formation is not listed as a significant hazard at the thawing and brining steps of the scrombotoxic species. A review of records indicated that products may be thawed at room temperature and may exceed [redacted]F for an undetermined period.

- Monitoring record data is missing, 21 CFR 123.6(c)(7). Your firm's brining logs do not always record the required information. For example, the date/time product is removed from the brine is not documented. Also, your firm is to review its incoming product labels as a control step for the hazard of *C. botulinum* and document such review on the invoice. Your firm is not recording this check on their invoices.

- Monitoring procedures implemented are inadequate, 21 CFR 123.6(b). For example, your firm does not document the critical limit of the fish to brine ratio during the brining of hot smoked scrombotoxic species or of hot/cold smoked salmon. The brining log does not include any entries for this critical parameter.

- Corrective action listed in the plan is not appropriate, 21 CFR 123. For example, the corrective action at smoking for hot smoked products is not specific enough to assure that the product will be acceptable if re-worked. Your plan only states that you will increase the temperature and processing time.

21 CFR 123.16 requires that you include in your HACCP plans how you are controlling the food safety hazard associated with the formation of toxin by Clostridium botulinum for at least as long as the shelf life of the product under normal and moderate abuse conditions. The critical limit listed is [redacted] water phase salt (wps). Laboratory results provided to our investigators indicate levels of [redacted] wps in trout and whitefish. You need to demonstrate that the recipes stipulated in your HACCP plan consistently result in the specified critical limit. Documentation should also be provided that the recipe used consistently results in the specified critical limit pH level achieved in pickled herring.

- A hazard is not being controlled, 21 CFR 123.6(b). For example, parasites are not being controlled for cold smoked aquacultured salmon. Your firm receives aquacultured salmon with a certificate of compliance from their supplier, however, typically the product is intended to be cooked prior to consumption. Your firm is not controlling this hazard, ie., by freezing or cooking, for this cold smoked product.

- Sanitation monitoring is inadequate, 21 CFR 123.11(b). For example, there were numerous sanitation deficiencies listed on the FDA 483. Also, the sanitation checklist does not include the monitoring of cross contamination or protection of the food from adulterants. There were GMP observations noted for both of these areas during the inspection.

- Product specifications do not exist and no affirmative steps are taken, 21 CFR 123.12(a)(2)(ii). Your firm imports herring from Canada, however you do not have any written product specifications for the product nor are there any affirmative steps taken. .

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 279-1675, Extension 113.

Sincerely,

John R. Marzilli
District Director
New England District Office